DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAY 19 2000

7434 '00 MAY 22 P1:34

The Honorable Peter DeFazio
Member, U.S. House of Representatives
151 West 7th Avenue, Suite 400
Eugene, Oregon 97401-2649

Dear Mr. DeFazio:

Thank you for your letter of April 19, 2000, on behalf of your constituent, Mr. David Oaks, Eugene Director of the Support Coalition, International of Eugene, Oregon, regarding possible action by the Food and Drug Administration (FDA) with respect to electroconvulsive therapy (ECT) devices.

In 1982, the American Psychiatric Association petitioned FDA to generally reclassify ECT devices from Class III (premarket approval) to Class II (special controls), a lesser regulatory class. After considering scientific data and information submitted in the petition, as well as information in its own files, FDA published a proposal in the Federal Register of September 5, 1990, to reclassify ECT devices to Class II for treatment of severe depression only (copy enclosed). FDA believes there is a lack of certain basic research information on ECT, and this is the reason why the proposed reclassification is limited. FDA believes that the available scientific evidence supports the use of ECT in the treatment of severe depression in cases where drug therapy has proven ineffective, but does not support the use of ECT for schizophrenia or other indications.

The proposal provided for a 60-day period for public comment, which was extended at least once. Comments, such as those that you have addressed, that continue to be received by the Dockets Management Branch will be forwarded to the Center for Devices and Radiological Health for consideration prior to publication of the final rule.

82P-0316

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Thank you again for contacting us about this matter. If you have further questions, please let us know.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosure

cc: Dockets Management Branch

PETER A. DeFAZIO
4TH DISTRICT, OREGON

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Congress of the United States
House of Representatives

PLEASE RESPOND TO:
☐ 2134 RAYBURN HOUSE OFC. BLDG.
WASHINGTON, DC 20515-3704
(202) 225-6416

☑ 151 WEST 7TH AVE. #400
EUGENE, OR 97401-2649
(541) 465-6732
1-800-944-9603

☐ P.O. BOX 1557
COOS BAY, OR 97420-0333
(541) 269-2609

☐ P.O. BOX 2460
ROSEBURG, OR 97470-0511
(541) 440-3523

☐ Peter.DeFazio@mail.house.gov

April 19, 2000

Dr. Jane Henney, Commissioner
Food and Drug Administration
5600 Fishers Lane, Room 15-55
Rockville, MD 20857

Dear Dr. Henney:

According to my constituent, David Oaks, Eugene director of the Support Coalition, International, the Food and Drug Administration (FDA) has not tested and approved electroshock devices for safety and efficacy.

I urge the FDA to establish standards for electroshock equipment and make rigorous testing and monitoring a top priority.

Thank you for your help. Please call my aide, Joella Ewing, if you have any questions.

Sincerely,

PETER DeFAZIO
Member of Congress

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Enclosure

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